

Notice of Allowability

Application No.

09/489,667

Applicant(s)

DONOVAN, STEPHEN

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/27/06.
2. ☒ The allowed claim(s) is/are 69,71-73,75 and 76.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12/12/00
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of the Claims

1. Claims 69, 71-73, 75 and 76 are pending.

Applicant's amendment filed April 27, 2006 is acknowledged, and applicants' response has been fully considered. Claims 77-80 have been cancelled. Therefore, claims 69, 71-73, 75 and 76 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 77-80 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 4 in the amendment filed April 27, 2006.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Examiner's Amendment to the Specification:

-Please replace the term "Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-amide" at page 26, Table 1, item (1) with the term "Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-amide (SEQ ID NO:1)"

-Please replace the term "Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly" at page 26, Table 1, item (2) with the term "Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly (SEQ ID NO:2)"

Art Unit: 1656

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys” at page 26, Table 1, item (3) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys (SEQ ID NO:3)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg” at page 26, Table 1, item (4) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg (SEQ ID NO:4)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-OMe” at page 26, Table 1, item (5) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-OMe (SEQ ID NO:5)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-OMe” at page 26, Table 1, item (6) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-OMe (SEQ ID NO:6)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg-OMe” at page 26, Table 1, item (7) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg-OMe (SEQ ID NO:7)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-OEth” at page 26, Table 1, item (8) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-OEth (SEQ ID NO:8)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-OEth” at page 26, Table 1, item (9) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-OEth (SEQ ID NO:9)”

Art Unit: 1656

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg-OEth” at page 26, Table 1, item (10) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-Gly-Lys-Arg-OEth (SEQ ID NO:10)”

-Please replace the term “Arg-Pro-Lys-Pro” at page 27, Table 1, item (11) with the term “Arg-Pro-Lys-Pro (SEQ ID NO:11)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe” at page 27, Table 1, item (12) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe (SEQ ID NO:12)”

-Please replace the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly” at page 27, Table 1, item (13) with the term “Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly (SEQ ID NO:13)”

-Please replace the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Phe-Phe-Trp-Leu-Met-amide” at page 27, Table 1, item (14) with the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Phe-Phe-D-Trp-Leu-Met-amide (SEQ ID NO:14)”

-Please replace the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Phe-Phe-Trp-Leu-Met-Gly” at page 27, Table 1, item (15) with the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Phe-Phe-D-Trp-Leu-Met-Gly (SEQ ID NO:15)”

-Please replace the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Trp-Phe-Trp-Leu-Met-amide” at page 27, Table 1, item (16) with the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Trp-Phe-D-Trp-Leu-Met-amide (SEQ ID NO:16)”

-Please replace the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Trp-Phe-Trp-Leu-Met-Gly” at page 27, Table 1, item (17) with the term “Arg-D-Pro-Lys-Pro-Gln-Gln-D-Trp-Phe-D-Trp-Leu-Met-Gly (SEQ ID NO:17)”

Art Unit: 1656

-Please replace the term "Arg-Pro-Cys-Pro-Gln-Cys-Phe-Tyr-Gly-Met-amide" at page 27, Table 1, item (18) with the term "Arg-Pro-Cys-Pro-Gln-Cys-Phe-Tyr-Gly-Pro-Met-amide (SEQ ID NO:18)"

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be the closest art to the claimed invention. Foster *et al.* (USPN 5,989,545; WO 96/33273) teach an agent specific for nociceptive afferent neurons, where the agent comprises a targeting moiety (TM) coupled to a clostridial neurotoxin in which the H_C part of the heavy chain is removed or modified, and the targeting moiety can be nerve growth factor, TNF, endorphin, bradykinin, antibodies or other ligands binding to the receptors (e.g., conjugate of LH_N/A and NGF). However, the references do not teach an agent comprising a botulinum toxin H_N, a botulinum toxin L chain and no functional H_C domain, where the modified botulinum toxin is covalently coupled to substance P. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/489,667

Page 6

Art Unit: 1656

Chih-Min Kam, Ph. D.
Primary Patent Examiner



primary

**CHIH-MIN KAM
PATENT EXAMINER**

CMK

June 29, 2006